ABA Section of Environment, Energy, and Resources
AMERICAN BAR ASSOCIATION

COMMITTEE ON PESTICIDES, CHEMICAL REGULATION & RIGHT-TO-KNOW COMMITTEE

TSCA REFORM LEGISLATION UPDATE AND PRIMER

TSCA AMENDMENTS OF 2016

JUNE 28, 2016

WELCOME & INTRODUCTIONS

Moderator: Larry Culleen, Partner, Arnold & Porter LLP

Honored Guest: Jim Jones, Assistant Administrator, US EPA

Featured Panelists:

Alex Dunn, Executive Director & General Counsel, Environmental Council of the States

Mike Walls, VP Regulatory & Technical Affairs, American Chemistry Council

Richard Denison, Lead Senior Scientist, Environmental Defense Fund

Ernie Rosenberg, President & CEO, American Cleaning Institute

Lynn Bergeson, Managing Partner, Bergeson & Campbell

Keith Matthews, Counsel, Sidley Austin LLP

REVIEW OF MEETING AGENDA

Remarks of EPA Assistant Administrator (Jim Jones)

Tutorial on Significant Sections

- Section 4 – Testing (Lynn Bergeson)
- Section 5 – Manufacturing and New Uses (Lynn Bergeson)
- Section 6 – Prioritization, Risk Evaluation/Management (Richard Denison)
- Section 8 – Inventory (Keith Matthews)
- Section 14 – Confidentiality (Keith Matthews)
- Section 18 – State – Federal Relationship (Alex Dunn)
- Section 26 – Administration, Fees, Policies and Guidance (Mike Walls)

Round Up of Important Points of View

- Environmental Interest Groups (Richard Denison, EDF)
- State Agencies (Alex Dunn, ECOS)
- Manufacturers (Mike Walls, ACC)
- Processors and Formulators (Ernie Rosenberg, ACI)

Open Discussion and Q&A

STATUS OF TSCA AMENDMENTS

FRANK R. LAUTENBERG CHEMICAL SAFETY FOR THE 21ST CENTURY ACT

- **House of Representatives voted 403 – 12; May 24**
- **Senate passed bill be unanimous consent; June 7**
- **Signed by President Obama on June 22, 2016**

TUTORIAL

§4. TESTING

Expands EPA authority to require development of information

- Authorizes administrative orders and consent agreements in addition to rule making
- Permits EPA to require testing needed for prioritization
- New authority does not require EPA findings
- May not be used to establish a minimum data set

New section concerns vertebrate animal testing and requires EPA to:

- Reduce and replace such testing to extent practicable, scientifically justified, etc.
- Develop and implement strategic plan to promote alternative test methods

TUTORIAL

§5. NEW CHEMICALS/SIGNIFICANT NEW USES

- **Retains certain basic requirements**

  90-day review period, extensions permitted
- **Requires EPA determination on all Notices**
- **Three alternative determinations:**
  - NC/SNU *presents* an unreasonable risk
  - Available information is *insufficient* **or** NC/SNU *may present* unreasonable risk **or** it has *substantial production and exposure*, or
  - NC/SNU *not likely* to present unreasonable risk

§5. NEW CHEMICALS/SIGNIFICANT NEW USES (CONT'D)

- EPA required to regulate under 1 and 2
- Limits ability to regulate articles compared to TSCA, but
- Requires EPA also to apply a SNU rule under 1 and 2 or explain its "why not" reasoning

How the Lautenberg Act works

Existing Chemicals

EDF ENVIRONMENTAL DEFENSE FUND
Finding the ways that work

Enforceable Deadlines (can be extended up to 2 more years)

9-12 Months — Up to 3 Years — Up to 2 Years

Prioritization | **Determination** | **Risk Management**

85,000 chemicals on TSCA Inventory

Inventory "reset": EPA identifies active, inactive chemicals

High Priority
May present an unreasonable risk due to potential hazard and exposure path
EPA to designate at least 20 by 3.5 years

Low Priority
Is not high-priority; can be judicially challenged
EPA to designate at least 20 by 3.5 years

Not enough information
Request/require testing (can extend deadline by 90 days)

If information still insufficient, becomes high-priority

First 10 Work Plan chemicals
- Designate w/in 6 mos
- Not preemptive until final EPA action

Company-requested
- Specific criteria
- ≤ 50% of number EPA initiates
- Company pays full cost (50% if drawn from Work Plan)
- Not preemptive until final EPA action

Risk Evaluation

EPA must establish scope within 6 months

1

Does present unreasonable risk

- EPA must impose prohibitions or restrictions by rule necessary to eliminate the risk; cost used to select among options
- EPA imposes full ban of one or more uses; must also consider availability of viable, safer alternatives

2

Does not present unreasonable risk

2

Not enough information *If information is insufficient or more is needed, can require testing and issue an order to get additional data*

1 **Preemption Triggered** 2

During EPA review (3.5 years maximum)
New state restrictions on high-priority chemicals are prohibited except via waiver
Existing state actions remain in effect
Only applies to uses, risks within scope of EPA's review. States can readily get waiver if basic criteria are met or if action was proposed before review began.

After final EPA action (either no unreasonable risk or regulation if risk found)
State restrictions on production, distribution, processing or use taken after 4/22/16 are generally preempted if they apply to the same use/risk EPA addressed.
Other state actions (e.g., reporting or disclosure remain in effect or can be taken.
States can seek waiver.

Safety standard: "No unreasonable risk to human health or the environment."
- Based solely on risks to health/environment
- EPA cannot consider costs
- Eliminates "least burdensome" requirement

Key
= main process steps
= final agency action
= interim info-collecting step

TUTORIAL

§6. PRIORITIZATION, RISK EVALUATION, RISK MANAGEMENT OF EXISTING CHEMICALS

- **Adds prioritization**
- **Includes timelines**
- **Specifies minimum number of cases**
- **Prioritization applies risk-based screening process to designate high- versus low-priorities**
  - High-priority: *May present* an unreasonable risk because of *a potential hazard* and *a potential exposure*
  - Low-priority: Does not meet this standard
- **Where information is insufficient to support low-priority, default decision is high-priority**
- **Specifies high-priority categories**

TUTORIAL

§6. PRIORITIZATION, RISK EVALUATION, AND RISK MANAGEMENT OF EXISTING CHEMICALS (CONT'D)

- Risk Evaluation process determines whether chemical *presents* an unreasonable risk
- Chemicals found to present unreasonable risk must proceed to EPA risk management action
- Determinations regarding low-priorities and substances that do not present an unreasonable risk can be subject to judicial challenge
- [§9.] Retains EPA mandate to refer risks to another agency in certain cases – but adds mandate for EPA to address risk if other agency does not take timely action

§6. PRIORITIZATION, RISK EVALUATION, AND RISK MANAGEMENT OF EXISTING CHEMICALS (CONT'D)

- For chemicals that present an unreasonable risk, EPA is required to take timely risk management action
- TSCA's "least burdensome" language deleted; simplified procedural requirements
- EPA must consider/publish statement on certain cost-benefit aspects
- When EPA prohibits one or more uses, EPA also must consider availability of *technically and economically feasible alternatives*
- Allows for exemptions if certain requirements can be met
- Final §6 rules and associated risk evaluations can be subject to judicial review

TUTORIAL

INFORMATION GATHERING AND CBI

§8. Reporting and Retention of Information

- **Requires continued use of certain nomenclatures**
- **Includes Inventory "reset" process involving:**
  - ➢ Reporting rule to obtain information on *active chemicals*
  - ➢ Manufactured/imported/processed during previous 10-years
  - EPA to designate chemicals as *active* or *inactive*
  - Status of *inactive* chemicals can be changed by notice to EPA
  - EPA to review and approve/deny CBI claims made for chemical identity

TUTORIAL

INFORMATION GATHERING AND CBI (CON'T)

§14. Confidential Information

Revises and replaces TSCA Section 14

- **New section considers *information not protected from disclosure,* including that on*:***
- **Banned or phased-out chemicals, with certain limitations**
- **Health and safety studies**
  - "does not authorize the disclosure of any information, including formulas (including molecular formulas (including molecular structures) of a chemical…, that discloses processes used…or, in the case of a mixture,… the portion of the mixture comprised by any of the chemical substances in the mixture"
- **10 year limitation on CBI protection, subject to renewals**
- **Requires assertion and substantiation of most CBI claims**

TUTORIAL

§ 18. STATE-FEDERAL RELATIONSHIP

- **Preemption was one of the most debated aspects of TSCA reform**
- **Grandfathers:**
- **States' actions taken before April 22, 2016**
- **Action taken pursuant to state laws in effect August 31, 2003 (*e.g.,* Prop 65)**
- **After final EPA action, prohibits states from establishing or continuing to enforce statutes, regulations, etc., that would:**
  - Duplicate information requirements under TSCA §§4, 5, or 6 actions
  - Prohibit or restrict a chemical after EPA has determined that a chemical does not present an unreasonable risk or issued a final §6(a) rule, or
  - Subject a chemical to the same notification of use already established in §5 SNU rule

TUTORIAL

§ 18. STATE-FEDERAL RELATIONSHIP

- **Exceptions: Past and future actions are not preempted when the state action:**
  - Is not a restriction/implements a reporting or other information obligation not otherwise required by TSCA or any other federal law
  - Is adopted under the authority of another federal law
  - Under certain circumstances, is adopted under a state law related to water quality, air quality, or waste management
  - Is identical to a requirement prescribed by EPA (with penalties no less stringent than available to EPA)
  - Relates to a low-priority chemical or to a new chemical

§ 18. STATE-FEDERAL RELATIONSHIP

***Additional provisions*:**

- **Waivers: Allows states to seek a waiver from preemption restrictions during or after EPA review**
- **Note: Preemption prohibits states from imposing new laws once EPA takes certain TSCA actions, such that a waiver granted may remain in effect only until such time as EPA publishes a §6(b) risk evaluation, after which:**
  - Final preemption applies if EPA finds no unreasonable risk or,
  - If EPA finds unreasonable risk, states can act until the RM action is final
- **Savings: Ensures that preemption does not affect state or federal common law rights and private remedies (*e.g.*, tort actions)**

TUTORIAL

§26. ADMINISTRATION AND FEES

- **Expands EPA's authority to collect fees to defray costs subject to certain limitations**
  - Applies to manufacturers and processors
  - Fee rule developed in consultation with industry
  - Fund and accountability provisions

- **Requires EPA to:**
  - Use the best available science and weight of evidence
  - Develop needed policies, procedures, and guidance (PP&G)
  - Establish Science Advisory Committee on Chemicals (SACC)

INDUSTRY PERSPECTIVE ON KEY MODIFICATIONS

- Strengthened Preemption Provisions
- Scientific Standards
- Affirmative Determinations

OPEN DISCUSSION

QUESTION & ANSWER SESSION